

MEMORANDUM OF MEETING

August 20, 1999

6508 '00 MAY 12 P1:53

LOCATION: FDA, 200 C St., SW, Washington, DC 20204 (2:00 PM)

ATTENDEES:

FDA:

Robert Lake, Christine Lewis, Susan Pilch, Virginia Wilkening, Judy Krauss, Sharon Ross

Thomas J. Lipton Company:

Gert Meijer, David Blanchard, Bill Franke, Nancy Schnell, Steve Wheeler, Dan Dwyer (Kleinfeld, Kaplan and Becker)

SUBJECT: Petition for a health claim

The meeting was held at the request of the firm to discuss a potential health claim for vegetable oil sterol esters and reduced risk of heart disease. The firm expressed their intention to submit a health claim petition in the near future.

The firm discussed the proposed substance, qualifying levels, and recommended use, and also presented a proposed model claim and a summary of the scientific information supporting such a claim. The firm also presented a summary of the basis for two exemptions from health claim regulations they intend to request in their submission: the disqualifying level for fat and the 10% content level for one or more nutrients.

The firm asked for feedback on their potential health claim and for feedback on the basis for the exemptions, as presented during the meeting. FDA provided general guidance, but mentioned the need to review the material, such as would occur during the initial phase of a health claim review.

The firm also expressed their intention to begin a new advertising campaign on products containing vegetable oil sterol esters.

Attachments

- attendee sign-in sheet
- Lipton agenda for meeting, dated August 6, 1999

00P-1275

mmi

Meeting between FDA and Lipton
8/20/99, 2pm

Attendees

<u>Name</u>	<u>Affiliation</u>
Sharon Ross	OSN / FDA
Gert Meijer	Lipton / R & D
DAVID BLANCHARD	LIPTON
Bill Franke	Lipton
Dan Dwyer	Klenfeld Kaplan + Becker
Nancy Schnell	Lipton
Susan Pilch	OSN / FDA
Steve Wheeler	Lipton
Judith Kraus	OEN / FDA
Virginia Wilkening	OFL / FDA
Christine Lewis	OSN / FDA
Robert Lake	



Unilever

CONFIDENTIAL COMMERCIAL INFORMATION

Nancy L. Schnell
Deputy General Counsel - Marketing

6509 '00 MAY 12 P1:53

August 6, 1999

Susan M. Pilch
Food and Drug Administration
200 C Street, SW
Room 1830
Washington, DC 20204

Re: Proposed Petition for a Health Claim

Dear Ms. Pilch:

I am writing to confirm a meeting between representatives of FDA and Lipton to discuss a purposed petition for a health claim for vegetable oil sterol esters and reduced risk of heart disease. As we previously discussed by telephone, this meeting has been scheduled for August 20, 1999 at 2 p.m. at your office. We understand that you have allotted about one hour for our meeting.

The participants for Lipton will include William Franke, Ph.D. (Vice President Scientific & Regulatory Affairs), Gert Meijer, Ph.D. (Director of R&D for Nutraceuticals), Dan Dwyer (Kleinfeld, Kaplan & Becker), and myself. A purposed agenda is as follows:

Introduction - Proposed substance, qualifying levels, recommended use, and the health claim -	Dr. Franke
Presentation summarizing the scientific information supporting a health claim -	Dr. Meijer
Presentation summarizing the basis for exemptions from the disqualifying level for fat and from the 10% content level for one or more nutrients -	Mr. Dwyer
Discussion of questions -	All

The questions we would like to discuss during the meeting include the following:

48671.01 8/6/99

Unilever United States, Inc.

390 Park Avenue • New York, New York 10022
Telephone (212) 906-4573 • Facsimile (212) 318-3680

1. Are there any questions that should be addressed in the petition to facilitate FDA's review of our scientific information?

During the meeting, we will summarize the data, all of which show that vegetable oil sterol esters reduce blood cholesterol levels when consumed in fat-based foods.

These include: (1) A summary of 40 years of clinical studies on plant sterols which show that plant sterols, mainly non-esterified beta-sitosterol, are effective in lowering blood cholesterol levels. (2) European studies which demonstrate that vegetable oil sterol esters when consumed in spreads, are effective in lowering blood cholesterol levels. (3) A study completed in the United States which demonstrates that vegetable oil sterol esters when consumed in spreads are effective in lowering blood cholesterol levels when consumed as part of a Step 1 diet.

2. We assume you agree that in the context of a health claim the substance can be referred to as "vegetable oil sterol esters."

We would like to discuss whether we can also use a more "consumer friendly" term (such as "soybean extract") if the labeling explains that the term such as "soybean extract" refers to vegetable oil sterol esters. (This is done on current Take Control labeling, which was previously reviewed by FDA.)

3. Is the proposed qualifying level and recommended use appropriate?

A proposed minimum qualifying level and also the proposed maximum level per serving, will be 1.8 gram vegetable oil sterol esters equivalent to 1.1 gram of free phytosterols. The proposed recommended use, to be required in labeling will consist of language such as "Eat 2 to 3 servings per day of foods with vegetable oil sterol esters." Studies indicate that 1 gram of free phytosterols per day is associated with meaningful cholesterol reduction, and that consumption above 3 grams per day does not result in significant additional reduction therefore, Lipton believes that a consumption range of about 2 to 3 grams per day is optimal.

4. Is the proposed exemption from the disqualifying level for fat adequately expressed?

Vegetable oil sterol esters are soluble in fat and only appropriate for use in a fat-based carrier. Lipton will request that the health claim be applicable initially to two fat-based foods, vegetable oil spread and dressing for salad. Consumption of these foods with vegetable oil sterol esters would substitute for consumption of similar foods without this added ingredient. Therefore, no net increase in fat consumption is

anticipated. Further, these foods are low in saturated fat and cholesterol. Therefore, recommendation of these foods would be consistent with a recommendation for a diet low in saturated fat and cholesterol.

5. Is the proposed exemption from the requirement that the food contain at least 10% of certain nutrients (the "jelly bean" rule) adequately expressed?

A serving of dressing for salad (2 tablespoons) would not meet this technical requirement -- the 10% level. As will be discussed further during our meeting, an exemption from this requirement is appropriate because dressing for salad is a nutritional food that is always consumed with vegetables/other nutritional foods and is, therefore, associated with reasonable nutrient levels. Dressing for salad is not similar to the types of foods (such as jelly beans) that were meant to be precluded from being labeled with health claims. Moreover, the recommended daily use of 2 to 3 servings of vegetable oil sterol ester-containing product would provide significant nutrient levels on a daily basis.


6. Is the proposed health claim appropriately expressed?

The health claim we are considering is "vegetable oil sterol esters may help lower bad (LDL) cholesterol levels and reduce the risk of heart disease as part of a low saturated fat and cholesterol diet."

The information in this letter is confidential information, exempt from public disclosure under the Freedom of Information Act and FDA regulations.

We look forward to discussing these issues with you on August 20. If prior to that time you have any questions, please call me (212-906-4573) or Dan Dwyer (202-223-5120). Thank you for your assistance with this matter.

Sincerely,

A handwritten signature in cursive script that reads "Nancy L. Schnell". To the right of the signature, the word "cc:" is written in a smaller, less legible script.

Nancy L. Schnell
Deputy General Counsel-Marketing and
Regulatory

NLS/DLT